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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,082	11/17/2003	Keif M. Fitzgerald	ENDOV-66188	4869

24201 7590 09/30/2005

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,082

Applicant(s)

FITZGERALD ET AL.

Examiner

Melissa A. McCorkle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to action received on 2/15/2005.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitehouse et al (4,743,265.)

Whitehouse discloses an elongated catheter (18 and 20 together) having a distal end and a proximal end with a catheter handle (14 and 16) secured to the elongated catheter member (column 4, lines 34-37) and a platform (12) removably secured to the catheter handle (see figure 3).

With respect to claim 18, Whitehouse discloses the removable platform comprising protruding stabilizers (30a and 30b; column 4, lines 10-14).

With regards to claim 20, Whitehouse discloses the removable platform (12) slidably secured (40a and 40b; column 5, lines 30-53) to the catheter handle (14 and 16).

With regards to claim 24, the elongated catheter member includes an inner member (20) and an outer member (18; column 4, lines 20-22).

With regards to claim 25, the catheter handle (14 and 16) is slideable with respect to the outer member (18; 28a and 28b with 56a and 56b).

With regards to claim 26, the catheter handle includes structure securing the catheter handle to the outer membrane (28a and 28b with 56a and 56b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Hakky et al (6,113,577).

Whitehouse discloses the claimed invention as discussed above. However, Whitehouse does not teach the lower surface of the platform being curved.

Hakky et al teaches the use of a platform with a with a curved lower surface (16) in a intravascular access device positioning system in order to make the platform compatible, with the patient's skin and to allow a snug fit around a patients limb (column 7, lines 9-12).

It would have been obvious to one of ordinary skill in the art to modify platform of Whitehouse and curve it as taught by Hakky in order to make the platform compatible with the patient's skin and to allow a snug fit around a patients limb (column 7, 9-12).

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Burgermeister (2004/0193205).

Whitehouse et al discloses the claimed invention as discussed earlier. However, Whitehouse does not disclose a handle including a knob, which is slideable with respect to the handle and attached to the outer member of a catheter.

Burgermeister discloses an elongated catheter member (10), which includes an inner member (12) and an outer member (27), a catheter handle (14), which is slideable

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with respect to the outer member (27) and structure (see figure 1) securing the catheter to the outer member (27). Burgermeister further teaches the use of a knob (26), which is slideable with respect to the handle (see "Description of Preferred Embodiment", paragraph 0019) and is attached to the outer member (see figure 1) in order to steer a guidewire that is fed through the catheter (see "Description of Preferred Embodiment", paragraph 0019).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and include a knob that is slideable with respect to the handle and is attached to the outer member of the catheter in order to steer a guidewire that is fed through the catheter.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehouse et al in view of Burgermeister as applied to claims 27 and 28 above, and in further view of Gellman et al (2002/0055748).

With regards to claim 29, Whitehouse and Burgermeister disclose the claimed invention. However, they do not disclose the catheter handle including a cutter that is configured with an interior of the catheter handle.

Gellman teaches the use of a cutter (1312) configured with an interior of a catheter handle (1320; see "Detailed Description of the Preferred Embodiment," paragraph 0306) in order to cut through tissue that may become disposed between the inner and outer tubes ("Detailed Description of the Preferred Embodiment," paragraph 0306).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter configured within the interior of a catheter handle as taught by Gellman in order to cut through any tissue that may become disposed between the inner and outer tubes of the catheter.

With regards to claim 30, Gellman teaches the use of a cutter that is slideable with respect to the catheter handle (paragraph 0306) so that the cutter can be maneuvered to protrude from the distal tip of the catheter.

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter that is slideable with respect to the catheter handle as taught by Gellman so that the cutter can be maneuvered to protrude from the distal tip of the catheter.

With regards to claim 31, Gellman teaches the use of a cutter (1312) that is attached to a knob (1322) in order to engage the cutter with the knob and enable the knob to control the cutter and maneuver it to protrude from the distal tip of the catheter (paragraph 0306).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter attached to a knob as taught by Gellman in order to engage the cutter with the knob and enable the knob to control the cutter and maneuver it to protrude from the distal tip of the catheter (paragraph 0306).

With regards to claim 32, Gellman teaches the use of a slideable cutter attached to a catheter in order to allow the cutter to be maneuvered to protrude from the distal tip of the catheter.

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter slideably attached to the outer member. While Gellman does not teach an outer and inner member, the catheter that has the slideable cutter attached to it in Gellman has the same properties as the outer member of the catheter in Whitehouse and Burgermeister and therefore it would have been obvious to attach the cutter to any type of catheter, be it an inner or outer member in order to allow the cutter to be maneuvered to protrude from the distal tip of the catheter as taught by Gellman.

With regards to claim 33, Gellman discloses the use of a cutter that could be configured to longitudinally dissect the outer member of a catheter (1312).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Whitehouse and Burgermeister and include a cutter so that the cutter could be configured to longitudinally dissect⁵ the outer member of a catheter.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haindl (4,981,475) discloses a device for fastening a catheter. Bierman et al (5,192,273) discloses a catheterization system. Bierman (5,800,402) discloses a catheter anchoring system and method of use. Cardoso (6,093,169) discloses a nasal oxygen catheter. Gordon (4,224,937) discloses a stabilizing fitting for

an intravenous catheter. Chi (6,613,014) discloses a catheter hub with a detachable push device. Winston et al (6,752,800) discloses a catheter handle.

Response to Arguments

Applicant's arguments filed 2/15/05 have been fully considered but they are not persuasive. Regarding the applicant's arguments that the Whitehouse et al patent does not teach said subject matter, examiner disagrees and keeps same rejection as stated above. Whitehouse et al discloses all the structural elements in the claims, and the handles are capable of being removably secured to the base.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner provided motivation that is expressly stated in each of the prior art references for each of the rejections.

Regarding the argument that one in the art would not look to Gellman et al because it deals with cutting tissue; the device is well within the same field, namely the medical devices art, and therefore it is reasonable to assume that one of ordinary skill in the art would look to these devices to combine the teachings as stated in the rejection above and in the previous action. It is in the same field as the applicant's endeavor.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763



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